IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

JEFFREY T. TIERNEY, Plaintiff, v. AGA MEDICAL CORPORATION, Defendant.	)	4:11CV3098 MEMORANDUM AND ORDER

On November 18, 2011, judgment was entered dismissing this product liability action with prejudice after I ruled that Plaintiff's state-law claims for negligence and strict liability in tort are preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). On December 13, 2011, Plaintiff filed a motion to alter or amend the judgment pursuant to Rule 59 of the Federal Rules of Civil Procedure, or for relief from the judgment pursuant to Rule 60. Pursuant to Rule 15, Plaintiff also seeks leave to file an amended complaint, a copy of which is attached to the motion. Plaintiff's motion will be denied in all respects.

The product involved in this action is a medical device, an AMPLATZER® Septal Occluder ("ASO"), designed, manufactured and sold by Defendant. The ASO was surgically implanted to plug a hole in Plaintiff's heart in May 2005, but was removed after he was diagnosed in April 2008 with severe allergic reactions to the device's nickel content.

Because the FDA granted premarket approval ("PMA") to the ASO in 2001, Plaintiff is barred from bringing an action against Defendant which challenges the safety and effectiveness of the device. *See* *Riegel v. Medtronic, Inc.*, 552 U.S. 312

(2008).[1] In a brief submitted in response to a Rule 12(b)(6) motion filed by Defendant, Plaintiff tacitly conceded that the negligence and strict liability claims alleged in his complaint are preempted by federal law, but suggested that he should be permitted to amend the complaint to add claims alleging that "[t]he design of the ASO failed to comply with the FDA's specifications as contained in the Premarket Approval assessment" and that "[t]he ASO was manufactured in a manner that failed to comply with the FDA's specifications as contained in the Premarket Approval assessment." (Filing 11 at 1.) Plaintiff also indicated he needed "time to conduct discovery for the purpose of obtaining access to Defendant's PMA files in order to state his amended complaint with more specificity." (Filing 11 at 1.) In conclusion, he "ask[ed] this Court to deny Defendant's motion to dismiss as premature, and to permit him 180 days in which to conduct discovery and amend his Complaint." (Filing 11 at 3.)

I denied Plaintiff's request to conduct discovery and for leave to amend because he did not demonstrate an actual need for discovery and failed to identify an actual amendment being proposed. *See* NECivR 15.1(a) ("A party who moves for leave to amend a pleading . . . must file as an attachment to the motion an unsigned copy of the proposed amended pleading that clearly identifies the proposed amendments").[2] I then

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[1] The Supreme Court stated in *Riegel*, however, that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 330. Plaintiff must allege sufficient facts to show that Defendant "violated a federal requirement specific to the FDA's PMA approval of this Class III device." *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1207 (8th Cir. 2010). While "courts must exercise [care] in applying *Riegel*'s parallel claim principle at the pleading stage, particularly to manufacturing defect claims," *id.*, "a plaintiff must offer sufficient factual allegations to show that he or she is not merely engaged in a fishing expedition . . .." *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 597 (8th Cir. 2009).

[2] "Although leave to amend 'shall be freely given when justice so requires,' *see* Fed.R.Civ.P. 15(a), plaintiffs do not have an absolute or automatic right to amend." *U.S. ex rel. Lee v. Fairview Health Sys.*, 413 F.3d 748, 749 (8th Cir.2005). "[I]n order

granted Defendant's motion to dismiss Plaintiff's complaint for failure to state a claim upon which relief can be granted, and ordered that the action be dismissed with prejudice. When entering judgment, however, I specifically stated that Plaintiff is not precluded "from bringing an action predicated upon a factually supported claim that '[t]he design of the ASO failed to comply with the FDA's specifications as contained in the Premarket Approval assessment' or predicated upon a factually supported claim that '[t]he ASO was manufactured in a manner that failed to comply with the FDA's specifications as contained in the Premarket Approval assessment' *providing* that such an action complies with Rule 11 of the Federal Rules of Civil Procedure." (Filing 17 (emphasis in original).)

Now, in his proposed amended complaint, Plaintiff alleges that Defendant was negligent (1) "[i]n failing to follow the FDA's approved design and manufacture standards for a Class III device;" (2) "[i]n failing to warn Plaintiff of the potential for nickel reaction in patients prior to the insertion of this ASO device into Plaintiff;" and (3) "[i]n failing to comply with the mandatory FDA reporting requirement by not reporting incidents of adverse nickel reactions of ASO patients [of] which it became aware prior to May of 2005." (Filing 18-2, ¶ 6.) He also alleges for a strict liability claim that the ASO device was defective because it "deviated in a material way from the design and manufacturing specification required by the FDA as a part of and as a condition to, its pre-market approval as a Class III medical device," that the device did not have "adequate instructions and warnings of the dangers and risks of inserting this ASO device in a patient who had nickel reaction and allergy," and that "prior to May 2005 [Defendant] was aware of reported incidents of adverse reactions with the

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to preserve the right to amend the complaint, a party must submit the proposed amendment along with its motion." *Clayton v. White Hall Sch. Dist.*, 778 F.2d 457, 460 (8th Cir.1985). *See also In re 2007 Novastar Financial Inc., Securities Litigation*, 579 F.3d 878, 884 (8th Cir. 2009), and additional decisions cited in my memorandum and order entered on November 18, 2011 (filing 16 at 6-7).

use of the ASO device arising from nickel allergies, but did not report same to [the] FDA." (Filing 18-2, ¶ 14.)

Rule 59(e) permits a motion to alter or amend a judgment no later than 28 days after it has been entered. Such motions "serve the limited function of correcting manifest errors of law or fact or to present newly discovered evidence." *Wells Fargo Bank, N.A. v. WMR e-PIN, LLC*, 653 F.3d 702, 714 (8th Cir. 2011) (quoting *Lowry v. Watson Chapel Sch. Dist.*, 540 F.3d 752, 761 (8th Cir. 2008)). "A motion to alter or amend judgment cannot be used to raise arguments which could have been raised prior to the issuance of judgment" or "to introduce new evidence that could have been adduced during pendency of the summary judgment motion." *Preston v. City of Pleasant Hill*, 642 F.3d 646, 652 (8th Cir. 2011) (quoting *Concordia Coll. Corp. v. W.R. Grace & Co.*, 999 F.2d 326, 330 (8th Cir. 1993)).

Rule 59(e) motions based on new evidence are analyzed in the same manner as Rule 60(b)(2) motions. *Williams v. Hobbs*, 658 F.3d 842, 853-54 (8th Cir. 2011) (citing *United States v. Metro. St. Louis Sewer Dist.*, 440 F.3d 930, 933 n. 3 (8th Cir. 2006)). To prevail on such a motion the movant must show "(1) that the evidence was discovered after the court's order, (2) that the movant exercised diligence to obtain the evidence before entry of the order, (3) that the evidence is not merely cumulative or impeaching, (4) that the evidence is material, *and* (5) that the evidence would probably have produced a different result." *Id.* at 854 (emphasis in original; quoting *Miller v. Baker Implement Co.*, 439 F.3d 407, 414 (8th Cir. 2006)).

"Relief is available under Rule 60(b)(6) only where exceptional circumstances have denied the moving party a full and fair opportunity to litigate his claim and have prevented the moving party from receiving adequate redress." *Murphy v. Missouri Dept. of Corrections*, 506 F.3d 1111, 1117 (8th Cir. 2007) (quoting *Harley v. Zoesch*, 413 F.3d 866, 871 (8th Cir. 2005)). Relief under this rule is exceedingly rare as relief requires an "intrusion into the sanctity of a final judgment." *In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, 496 F.3d 863, 868 (8th Cir.

2007) (quoting *Watkins v. Lundell*, 169 F.3d 540, 544 (8th Cir. 1999)). "Exceptional circumstances are not present every time a party is subject to potentially unfavorable consequences as a result of an adverse judgment properly arrived at. Rather, exceptional circumstances are relevant only where they bar adequate redress." *Id.* (quoting *Atkinson v. Prudential Prop. Co., Inc.*, 43 F.3d 367, 373 (8th Cir. 1994)).

"Although leave to amend a complaint should be granted liberally when the motion is made pretrial, different considerations apply to motions filed after dismissal. *Dorn v. State Bank of Stella*, 767 F.2d 442, 443 (8th Cir.1985). A district court does not abuse its discretion in denying a plaintiff leave to amend the pleadings to change the theory of their case after the complaint has been dismissed under Rule 12(b)(6). *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 550 (8th Cir.1997); *Humphreys v. Roche Biomedical Labs., Inc.*, 990 F.2d 1078, 1082 (8th Cir.1993). The plaintiff must bear the consequences of waiting to address the court's rulings post-judgment. *First Nat'l Bank of Louisville v. Continental Illinois Nat'l Bank & Trust Co.*, 933 F.2d 466, 468 (7th Cir.1991)." *Briehl v. General Motors Corp.*, 172 F.3d 623, 629 (8th Cir. 1999). *Cf. United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009) ("[D]istrict courts in this circuit have considerable discretion to deny a post-judgment motion for leave to amend because such motions are disfavored, but may not ignore the Rule 15(a)(2) considerations that favor affording parties an opportunity to test their claims on the merits, particularly when a fraud complaint has been dismissed for failure to comply with the pleading requirements of Rule 9(b).").

Plaintiff contends that he should "be allowed to proceed in this cause on Defendant's failure to warn as Plaintiff plead[ed] in Division II and Division III of his original Complaint on the theory that such failure to warn is not pre-empted under by [sic] 21 U.S.C. § 360[k]." (Filing 18 at 1.) Plaintiff states that his proposed "failure to warn" claim is similar to a claim presented in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), in which a plaintiff alleged that a manufacturer of a Class III medical device had not reported incidents in which the device may have caused or contributed to a death or serious injury, or malfunctioned in such a way that

would likely cause or contribute to death or serious injury if the malfunction recurred, as required by 21 U.S.C. § 360i(a)(1) and 21 C.F.R. § 803.50(a). The Fifth Circuit ruled in *Hughes* that the plaintiff had alleged a "parallel" claim under Mississippi law which was not preempted by the Medical Device Amendments.

While I agree that the proposed amended complaint contains a claim which appears to be patterned after the claim alleged in the *Hughes* case, it bears no resemblance to the "failure to warn" claims alleged in Plaintiff's original complaint. Previously, Plaintiff alleged that Defendant failed "to warn [him] of the nickel content of this ASO," "to have issue[d] adequate warnings concerning the hazards to patients including Plaintiff that it's [sic] ASO could be inserted in patients with nickel allergies," "to warn doctors not to insert this ASO in patients with nickel allergy," and "to warn patients, including Plaintiff, of the ASO's nickel content." (Filing 1 at 4-5, ¶ 7.) Plaintiff effectively abandoned all of these "failure to warn" claims when he responded to Defendant's motion to dismiss,[3] as he stated that he only intended to amend his complaint to allege that the ASO was not designed and manufactured in accordance with the FDA's specifications.

Plaintiff has not shown that the dismissal of his "failure to warn" claims was manifest error, nor has he shown that any newly discovered evidence provides the basis for the proposed claim that Defendant "fail[ed] to comply with the mandatory FDA reporting requirement by not reporting incidents of adverse nickel reactions of ASO patients which it became aware prior to May of 2005." (Filing 18-2, ¶ 6.) In short, I find no grounds for granting Plaintiff relief under Rules 15, 59, or 60 with respect to this claim regarding an alleged violation FDA reporting requirements.

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[3] In granting Defendant's motion to dismiss, I observed that publicly available FDA documents concerning the ASO's PMA disclosed that the device is made from a wire mesh of Nitinol, a biocompatible nickel-titanium alloy, and expressly warned in "instructions for use" that patients allergic to nickel may suffer an allergic reaction to this device. (Filing 16 at 8.)

Plaintiff's other proposed "failure to warn" claim, alleging that there was not adequate warning provided about "the potential for nickel reaction in patients prior to the insertion of this ASO device into Plaintiff" (filing 18-2, ¶ 6), is facially indistinguishable from the claims that were previously alleged and dismissed. Plaintiff states in a brief filed in support of his pending motion that a recent patient guide posted on Defendant's website does not contain a warning about nickel allergies,[4] and suggests "[i]t is reasonable to assume that similar omissions were made in materials furnished to patients and also possibly to their physicians in 2005." (Filing 19 at 3.) Plaintiff has failed to show that he exercised due diligence to discover this information before his complaint was dismissed. Moreover, he has failed to demonstrate that the evidence is material to any of the FDA's PMA specifications, and has not even alleged that he received or relied upon such a patient guide before having his surgery. Plaintiff's proposed amendment is both untimely and futile, and will not be allowed. *See In re Medtronic, Inc.*, 623 F.3d at 1208 (district court did not abuse its discretion in denying post-judgment motion to amend which amounted to another "frontal assault on the FDA's PMA approval").

Finally, Plaintiff asks leave to amend to allege that Plaintiff "fail[ed] to follow the FDA's approved design and manufacture standards for a Class III device." (Filing 18-2, ¶ 6.) The judgment of dismissal stated that Plaintiff would be allowed to pursue a *factually supported* claim such as this, but the proposed amended complaint contains no supporting factual allegations whatsoever. Plaintiff merely asserts in his brief that "[t]he seriousness of [his] allergic reaction suggests that a higher percentage of nickel content may have been used in the device" than was described in the PMA documents. (Filing 19 at 3.) Even if this might be a reasonable inference, the proposed amended complaint only contains bare legal conclusions that the ASO was not designed or manufactured in accordance with FDA specifications. Because this allegation would not survive a motion to dismiss, Plaintiff's request for leave to amend will be denied

[4] The guide, an unauthenticated copy of which is attached to Plaintiff's motion (filing 18-3), appears to have been published in April 2008.

as futile. *See* *Moses.com Securities, Inc. v. Comprehensive Software Systems, Inc.*, 406 F.3d 1052, 1062 (8th Cir. 2005) ("Although the pleading standard is liberal, the plaintiff must allege facts—not mere legal conclusions—that, if true, would support the existence of the claimed torts."); *Wiles v. Capitol Indemnity Corp.*, 280 F.3d 868, 870 (8th Cir. 2002) ("While the court must accept allegations of fact as true when considering a motion to dismiss, the court is free to ignore legal conclusions, unsupported conclusions, unwarranted inferences and sweeping legal conclusions cast in the form of factual allegations.").

In summary, while giving due consideration to the principles of Rule 15(a)(2), I find no basis for granting Plaintiff's post-judgment motion for leave to amend. The dismissal of Plaintiff's action for the reasons stated in my previous memorandum and order (filing 16) was not the result of an error of law or fact which might provide grounds for relief under Rule 59(e), nor does Plaintiff have any newly discovered evidence which satisfies the requirements of Rule 59(e) and 60(b)(2). There also are no "exceptional circumstances" for granting Plaintiff relief under Rule 60(b)(6).

Accordingly,

IT IS ORDERED that Plaintiff's "motion to alter or amend and to amend complaint" (filing 18) is denied in all respects.

February 7, 2012. BY THE COURT:

Richard G. Kopf
Senior United States District Judge

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